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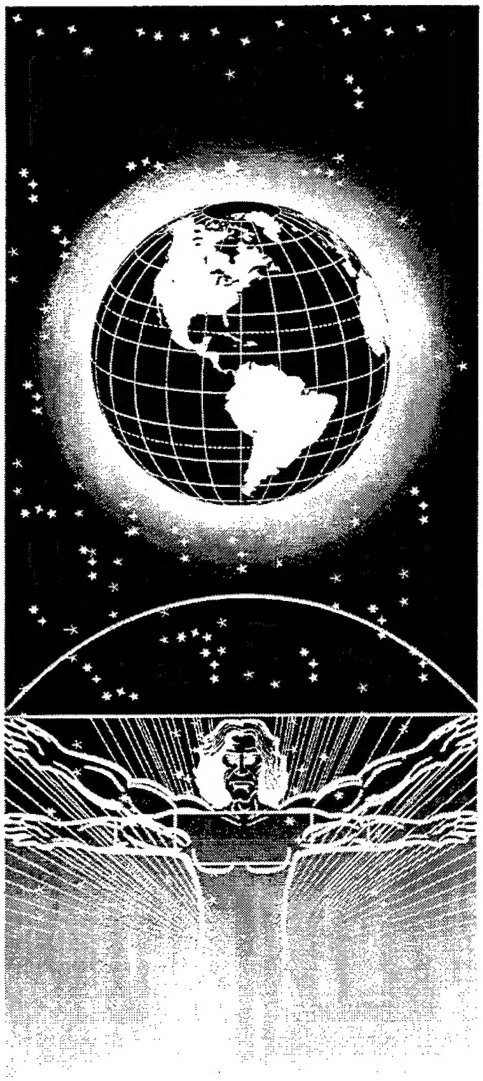

UNITED STATES AIR FORCE RESEARCH LABORATORY

TESTING AND EVALUATION OF THE ZOLL MEDICAL, CORP. M SERIES, CARDIAC MONITOR/MONOPHASIC & BIPHASIC DEFIBRILLATOR/PACER/SPO2/AED

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NOTICES

This final technical report was submitted by personnel of the Protective Systems Branch, Biodynamics and Protection Division, Human Effectiveness Directorate, Air Force Research Laboratory, AFMC, Brooks Air Force Base, Texas, under job order 7184-56-01.

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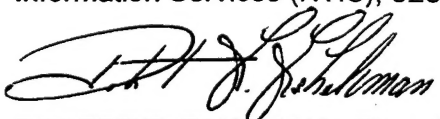

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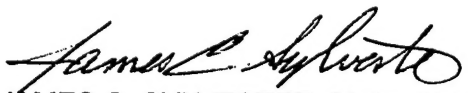

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14. ABSTRACT
The ZOLL M Series device combines a cardiac defibrillator, ECG display, AED (Automated External Defibrillator), advanced monitoring capabilities, and Noninvasive Transcutaneous Pacing (NTP) with communication, data printing and recording capabilities in a single lightweight portable instrument. The product is powered by both AC mains (115 VAC/60 Hz) and an easily replaced battery pack that is quickly recharged in the M Series device when it is connected to AC mains. The device is a versatile, automated external defibrillator with manual capabilities and may be configured to operate in manual advisory or semi-automated modes.

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BACKGROUND

ZOLL Medical, Corp., approached the Air Force Medical Equipment Development Laboratory (AFMEDL) in evaluating and approving ZOLL Medical Corp., M Series, Cardiac Monitor/ MonoPhasic and BiPhasic Defibrillator/Pacer/SpO_2/AED for use on board USAF aeromedical evacuation aircraft. Specific components of the MonoPhasic and BiPhasic units that underwent evaluation included ZOLL Medical Corp., M Series, MonoPhasic (SN: T9I00471) & BiPhasic (SN: T00A08248) Cardiac Monitor/Defibrillator/Pacer/ SpO_2/AED units. The ZOLL M Series devices represent the latest commercial off-the-shelf (COTS) technology. Throughout this report, the term M Series refers to both models, MonoPhasic and BiPhasic, and all internal and external components.

DESCRIPTION

(Partially extracted from ZOLL M Series Operator's Guide) (1)

The ZOLL M Series devices combine a cardiac defibrillator, ECG display, AED (Automated External Defibrillator), pulse oximetry (SpO_2), advanced monitoring capabilities, cardiac Noninvasive Transcutaneous Pacing (NTP) with communication, data printing and recording capabilities in a single lightweight portable instrument (Fig. 1). The devices are powered by either AC mains (115 VAC/60 Hz) or an easily replaced battery pack (ZOLL Smart Battery PD 4410) that is quickly recharged in the M Series device when it is connected to AC mains. The device can operate as an automated external defibrillator with manual capabilities and may be configured to operate in manual advisory or semi-automated modes. Information regarding the units operation, ECG, and other physiological waveforms are displayed on a large 4.5-inch diagonal field emissions display (FED) which provides high contrast and visibility. Self diagnostic tests are performed when the instrument is turned on and the unit is periodically tested during operation.

Defibrillator & Synchronized Cardioversion Functions

The M Series MonoPhasic model contains a DC defibrillator capable of delivering up to 360 joules of energy, whereas the BiPhasic model will deliver a maximum of 200 joules. The devices use paddles or disposable, pre-gelled, multi-function electrode (MFE) pads for defibrillation or synchronized cardioversion. Both models may be used in synchronized mode to perform synchronized cardioversion by using the R-wave of the patient's ECG as a timing reference.

Intended Use – Manual Operation

Use of the M Series device in the manual mode for defibrillation is indicated on victims of cardiac arrest where there is apparent lack of circulation as indicated by unconsciousness, absence of breathing, and absence of pulse. The product should be used only by qualified medical personnel for converting ventricular tachycardia to sinus rhythm or other cardiac rhythms capable of producing hemodynamically significant heart beats.

Intended Use – Semiautomatic Operation (AED)

The M series devices are designed for use by emergency care personnel who have completed training and certification requirements applicable to the use of a defibrillator where the device operator controls delivery of shocks to the patient. They are specifically designed for use in early defibrillation programs where the delivery of a defibrillator shock during resuscitation involving CPR, transportation, and definitive care are incorporated into a medically-approved patient care protocol. Use of the device in the semiautomatic mode for defibrillation is indicated on victims of cardiac arrest where there is apparent lack of circulation as indicated by unconsciousness, absence of breathing, and absence of pulse.

Semiautomatic Operation Contraindications for Use

The rhythm analysis function may not reliably identify ventricular fibrillation in the presence of an implantable pacemaker. Inspection of the electrocardiogram and clinical evidence of cardiopulmonary arrest should be the basis for any treatment of patients with implantable pacemakers. Do not use the rhythm analysis function during patient movement on a stretcher or in an ambulance or other conveyance. A patient must be motionless during ECG analysis. Do not touch the patient during analysis. Minimize all movement via stretcher or vehicle prior to analyzing the ECG. If using the device in an emergency ground vehicle, bring the vehicle to a halt before activating the analysis function. **Do not use the unit's advisory function on pediatric patients weighing less than 80lbs/36kg.**

Non-invasive Transcutaneous Cardiac Pacing

The M Series units incorporate a noninvasive temporary pacing option with a control panel located on the front of the monitor. The pacer is a demand type consisting of a pulse generator and ECG sensing circuitry. The output current of the pacemaker is continuously variable up to 140 mA and the rate is continuously variable from 30-180 pulses per minute (ppm).

Monitor

The patient's ECG is monitored by connecting the patient to the unit via the ECG patient lead cable, MFE pads, or through the paddles. Four seconds of ECG is presented on the display along with the following information:

- Averaged heart rate, derived from measuring R to R interval
- Lead selections - I, II, III, aVR, aVL, aVF, V (with ECG cable), PADDLES, or PADS
- ECG size- 0.5, 1.0, 1.5, 2.0, 3.0 cm/mV
- Pacemaker output in milliamps
- Pacemaker stimulus rate in pulses per minute
- Defibrillator output in joules
- Other operational prompts, messages, and diagnostic codes
- Monitoring or diagnostic ECG bandwidth is selectable.

Recorder Function

A strip recorder is provided to document events. The strip recorder normally operates in the delay mode (6 seconds) to insure capture of critical ECG information. The recorder may be activated manually by pressing the RECORDER button. It will be activated automatically whenever a defibrillation SHOCK is delivered, a heart rate alarm occurs, or the rhythm analysis function is activated. The strip recorder may also be configured to not print during these events.

Paddle – Electrode Options

The M Series devices will defibrillate, cardiovert and monitor ECG using either defibrillation paddles or ZOLL multi-function electrode pads.

The cardiac pacer function of the M Series requires use of the ZOLL MFE pads. Energy Select, Charge, and Shock controls are located on the paddles and front panel. When using MFE pads, the controls on the front panel of the unit must be used. Remove the multi-function cable from the apex paddle and connect the MFE pads to the multi-function cable when switching between paddles and pads.

The advisory function cannot be activated unless MFE pads are attached to the multi-function cable and used as the ECG monitoring lead.

Note: The MFE pads, and ECG electrodes (not the ECG cable) are disposable, single-use items.

Batteries

The M Series devices use an easily replaceable sealed lead-acid Smart Battery pack (PD 4410) that, when new and fully charged, will provide at least 2.5 hours of monitoring. Battery aging, defibrillator use, strip chart recorder use, and pacemaker operation will reduce this time. When a "LOW BATTERY" message appears on the display and the unit beeps twice in a row once a minute, the battery must be replaced and recharged.

Internal Battery Charger

Battery charging can be performed with the device. When the M Series devices are plugged into AC mains, the "CHARGER ON" indicators will operate in the following manner:

The orange-yellow "CHARGER ON" indicator will illuminate continuously whenever the device is turned "OFF" and charging the battery or turned "ON" with a battery installed.

The green "CHARGER ON" indicator will illuminate continuously whenever the unit is turned "OFF" and the installed battery has been fully charged to present capacity.

The green and orange-yellow "CHARGER ON" indicator will illuminate alternately when no Battery is installed in the unit or a battery charging fault has been detected.

When the devices are not connected to AC mains, the "CHARGER ON" indicator will remain extinguished.

Specifications

The following information defines the general specifications of the ZOLL M Series. Size: 6.8 in. high x 10.3 in. wide x 8.2 in. deep. Weight: 7.95 kgs (17.52 lbs) with EMI modifications (external ferrites) and accessories. Weight with X-treme pack and accessories: 9.12 kgs (20.12 lbs). Heart Rate Range: 0-300 BPM. Pacing Rate Range: 30-180 BPM. Pacing Amplitude: 0-140 mA. Pacing Rate: Varibable 0 to140 mA. Available Energy Range: 0-360 joules at 20 settings. Lead Selection: paddles, I, II, III, aVR, aVF, V, Paddles, or PADS. Printer speed: 12.5 or 25mm/sec.

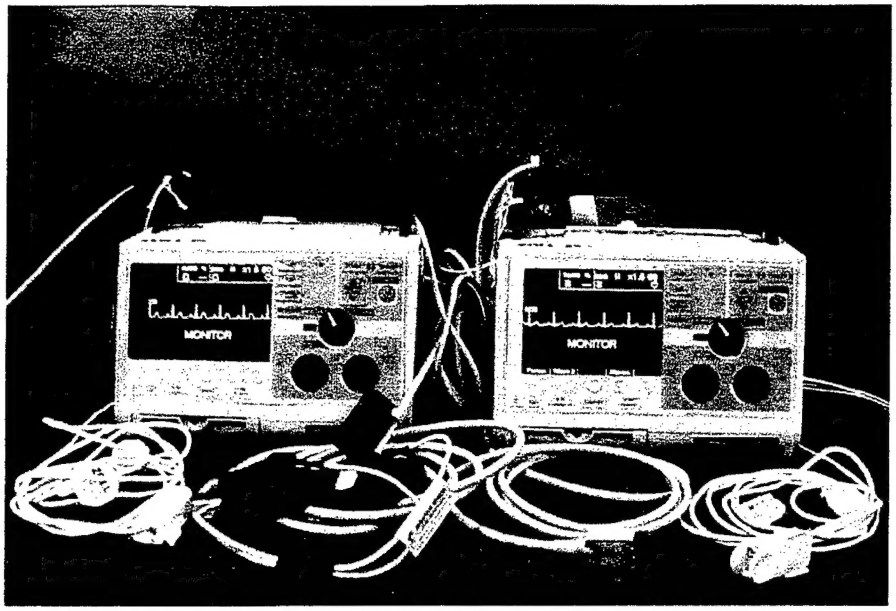

Figure 1. ZOLL MonoPhasic & BiPhasic Monitors

PROCEDURES

Test methods and performance criteria were derived from manufacturer's literature (1), various military standards (2-4,10), and nationally recognized performance guidelines (5). The Air Force Medical Equipment Development Laboratory Flight Performance Evaluation Procedures Guide and Testing Standards describes additional safety and human interface issues to be considered during equipment testing (6,11). A test setup and performance check were developed specifically for this product to verify proper functioning of the equipment under various testing conditions.

The M Series was subjected to various laboratory and inflight tests to observe and evaluate its performance under anticipated operational conditions.

1. Initial Inspection

2. Vibration

3. Electromagnetic Interference (EMI)

4. Thermal/ Humidity Environmental Conditions, encompassing:

    a. Hot Operation

    b. Cold Operation

    c. Humidity

d. Hot Temperature Storage

e. Cold Temperature Storage

5. Hypobaric

a. Cabin Pressure/Altitude

b. Rapid Decompression to Ambient

6. Explosive Atmosphere

7. Airborne Feasibility/Performance

INITIAL INSPECTION AND TEST PREPARATION

The M Series was inspected for quality of workmanship, production techniques, and possible damage incurred during shipment.

The M Series was checked to ensure it met safety requirements and operating characteristics established in National Fire Protection Agency (NFPA) 99 (7), Electrical Shock Hazards, AFI 41-203 (8), and Equipment Management in Hospitals, AFI 41-201 (9). Ground resistance and leakage current measurements were made at 115 VAC/60 Hz.

The M Series was examined to ensure it met basic requirements for human factors design as outlined in Mil-Std1472 (4).

A test setup and performance check were developed to evaluate the operation of the ZOLL M Series in accordance with manufacturer/customer specifications throughout the various testing conditions.

TEST SETUP

One of the following two analyzers was connected to the ECG port on the monitor and provided the ECG waveform for the M Series during the monitor portion of testing: the Lionheart Multiparameter Simulator or the Impulse 4000 Analyzer. The three ECG leads were attached to the corresponding color-coded receptacles on the analyzer. The Lionheart settings were the following: Lead Select, I/II; ECG amplitude, 1.0; and ECG BPM, beats per minute, 60. The Impulse selections were the following: ECG mode, Normal Sinus Group (NORM), and 60 beats per minute. The Impulse 4000 also analyzed the defibrillator portion of the M Series when it operated in the DEFIB mode. Additionally, the Impulse 4000 analyzed the pacer option of the M Series. Its settings were as follows: PACER mode, Internal 50 ohms load, PULSE, and TEST. The M Series was configured as follows: Lead Select, II; ECG size that allowed for the largest view of the waveform; pacer settings on 70 mA and 70 BPM when pacer was activated; PACER

mode selected; and ECG size control was adjusted so the SYNC marker was positioned on the upper portion of the QRS complex. The SpO_2 finger probe was connected to a Bio-Tek Index 2 Series SpO_2 Simulator.

Figure 2. Test Setup

PERFORMANCE CHECK

As the ZOLL M Series monitored the ECG waveform, defibrillator energy levels were selected and the paddles subsequently discharged into the energy determining device. The performance check included discharging the paddles at a high-energy level of 360 joules on the MonoPhasic unit and discharging at 200 joules on the BiPhasic unit. The ECG trace was used to visually confirm whether or not the defibrillators fired at the appropriate location on the waveform. The performance check concluded with the verification of the pacer output and recorder function. The Impulse 4000 monitored the pacer ensuring the accuracy of the pacing frequency and amplitude.

VIBRATION

Vibration testing is critical to determine the resistance of equipment to vibrational stresses expected in its shipment and application environments. This testing involved a set of operational tests performed along each of the ZOLL M Series' three axes - X, Y, and Z, with the M Series components mounted on the NATO litter segment on the vibration table as they would be in the aircraft (Fig. 3). They were subjected to vibration curves with similar levels and lengths as those derived from Mil-Std 810F, Annex C, (Fig. 4).

Figure 3. Vibration Table Mounting

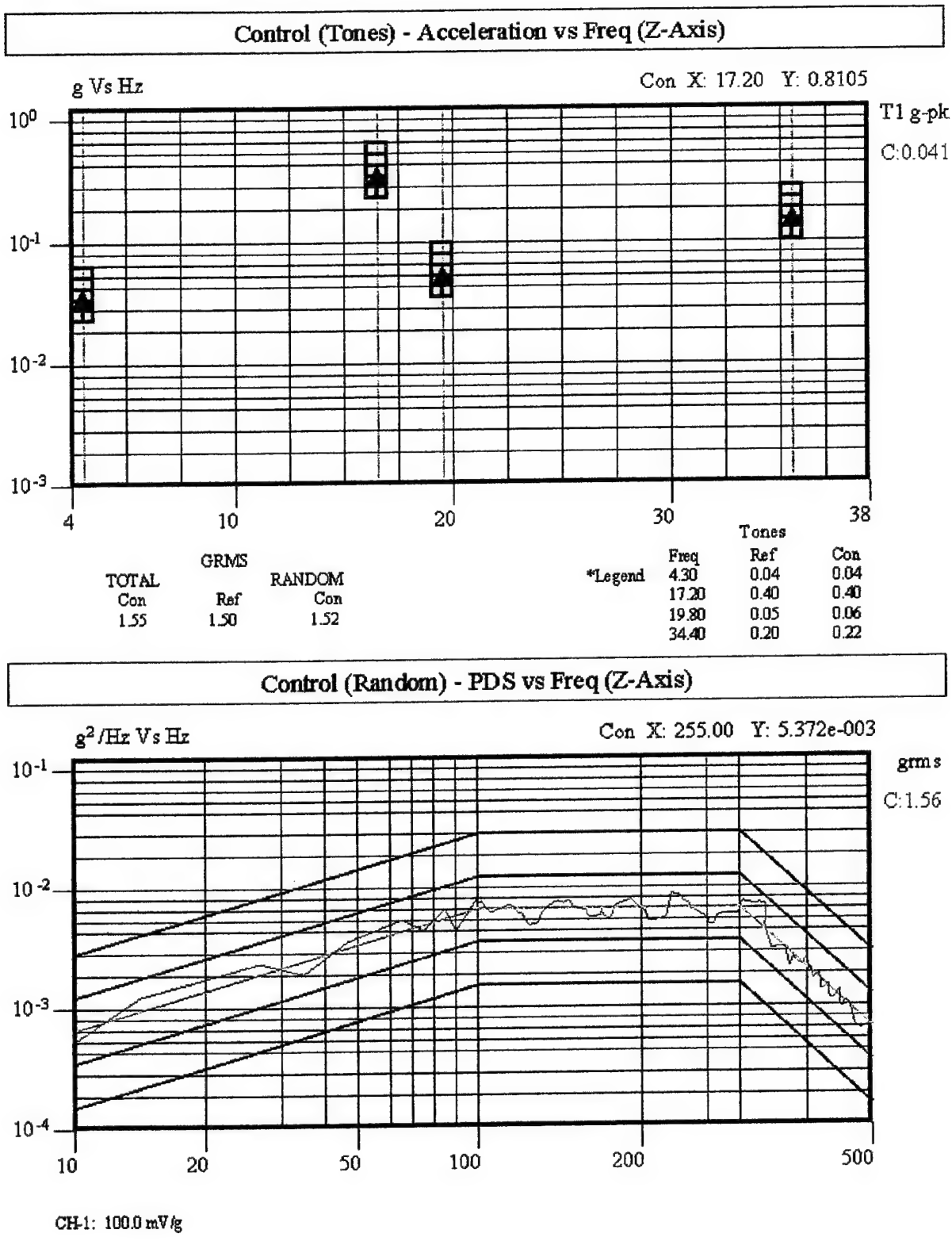

Figure 6. Sine-On-Random Z Axis based on Mil-Std 810F

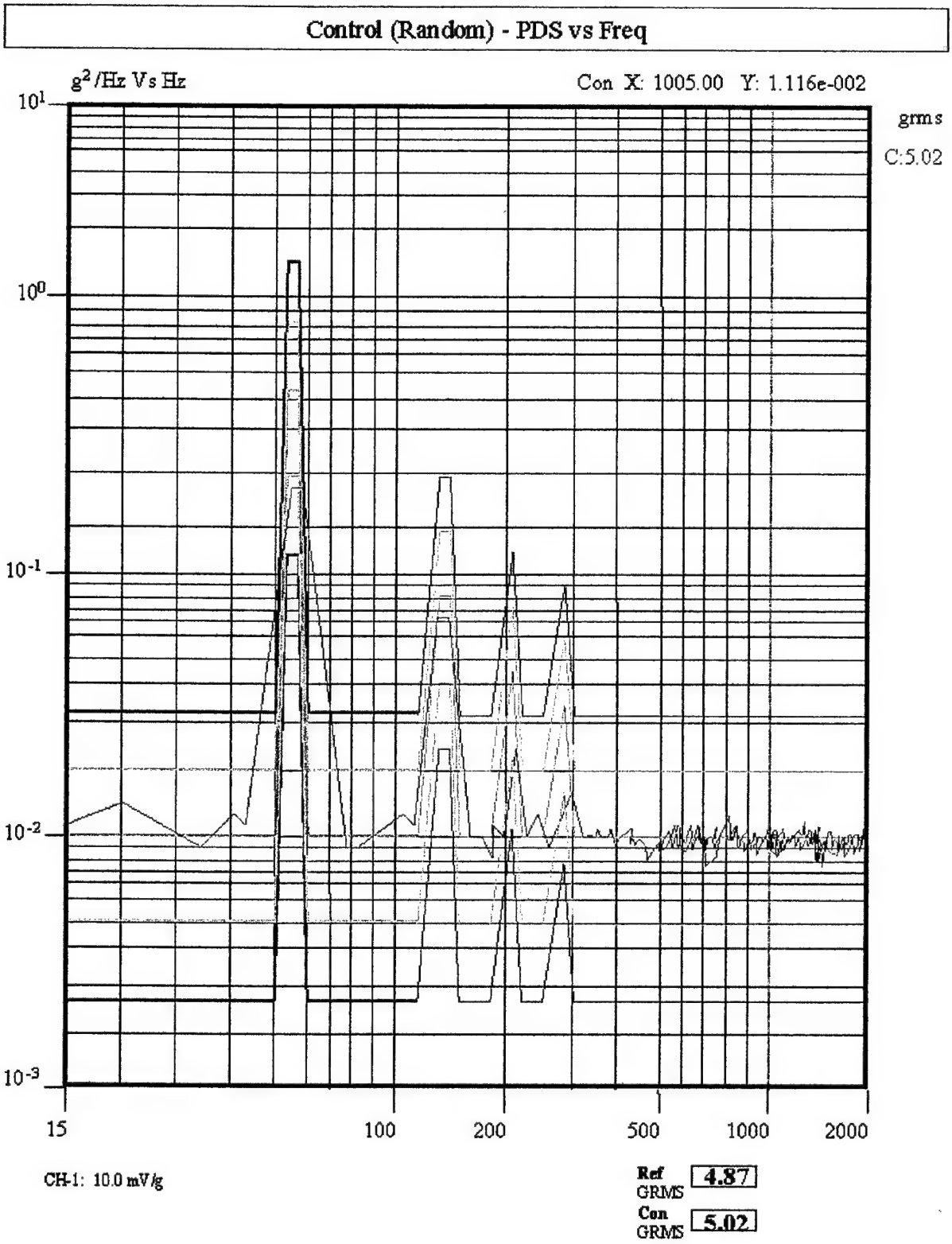

Figure 7. C-130 Turbo-prop based on Mil-Std 810F

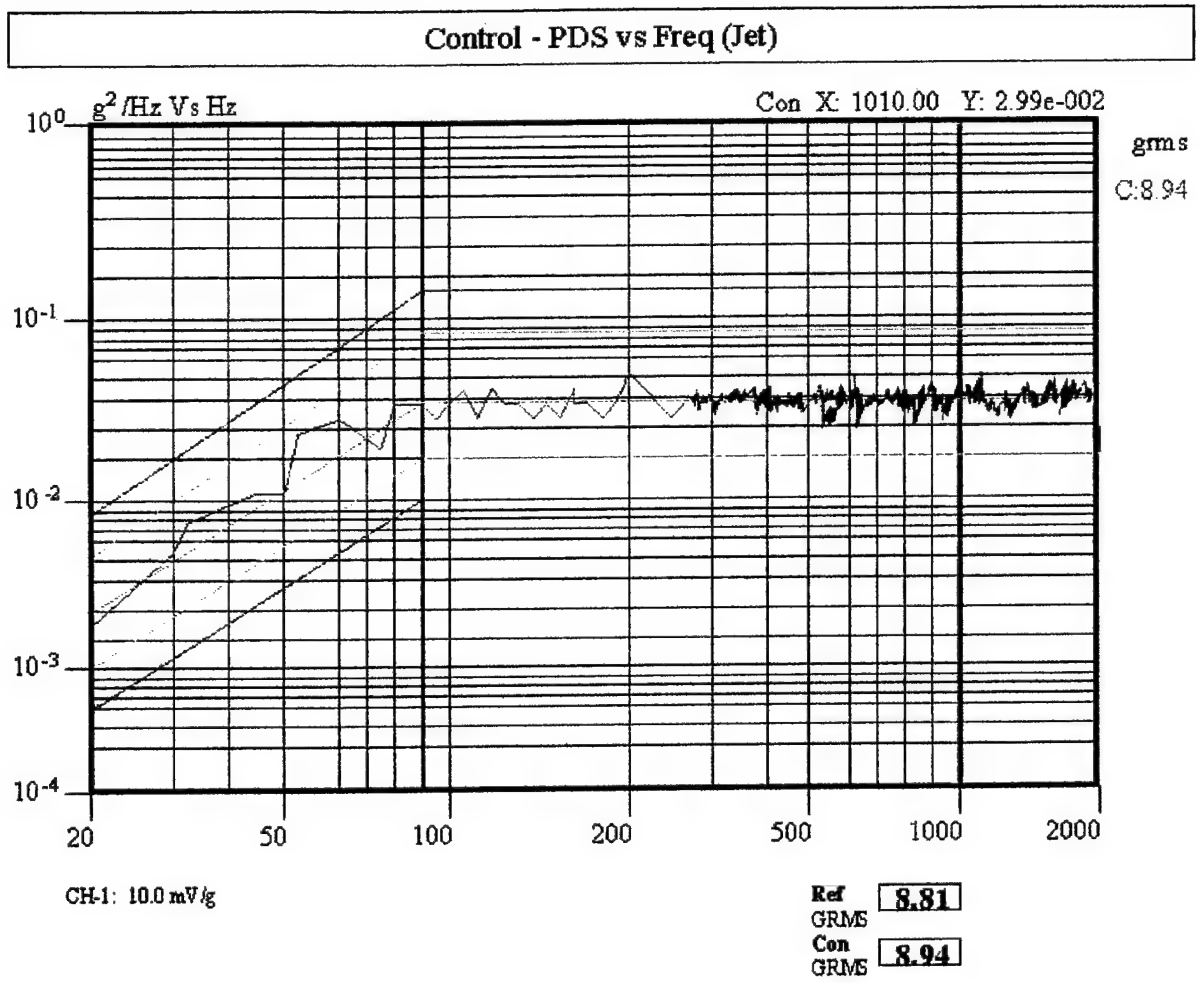

Figure 8. Random Jet based on Mil-Std 810F

ELECTROMAGNETIC COMPATIBILITY

Electromagnetic compatibility testing is a primary concern on USAF aeromedical evacuation aircraft. Ensuring the safety of everyone on board is the driving factor to assessing the effects of excessive electromagnetic emissions and their influence on aircraft navigation and communication equipment. Medical devices may be susceptible to fields generated by the aircraft equipment or other medical devices and malfunction in their presence.

The ZOLL M Series was evaluated for compliance with Mil-Std 461E (2). AFRL/SNZW Electromagnetic Research Laboratory located at Wright-Patterson AFB, Ohio performed the evaluation in their electromagnetic compatibility facility. WL/AAWA-2, Wright-Patterson AFB, evaluated the electromagnetic compatibility data and determined the airworthiness of the medical device. Specific tests conducted were as follows:

1. **RE102 - Radiated Emissions, Electric Field, (10 kHz - 18 GHz)**. For Air Force aircraft applications, radiated emissions were tested in a narrower range of frequencies from 2 MHz - 1 GHz. This test which measured the amount of EMI emitted by the equipment during its operation, was performed to verify that the device does not affect other pieces of equipment that may be susceptible to electromagnetic emissions (i.e., aircraft navigation and communication equipment).

2. **CE102 - Conducted Emissions, Power Leads, (10 kHz to 10 MHz)**. For Air Force aircraft applications, conducted emissions were tested throughout the entire band of 10 kHz - 10 MHz. This test which measured emissions generated by the medical device along its power supply lines, was performed to verify that operating the device using line power does not affect other items connected to the same power source, particularly aircraft systems.

3. **RS103 - Radiated Susceptibility, Electric Field, (10 kHz to 40 GHz)**. For Air Force aircraft applications, radiated susceptibility was tested in a narrower frequency range from 30 MHz - 18 GHz . This test evaluated the device's resistance to predefined levels of EMI generated by antennas both internal and external to the aircraft.

4. **CS101 - Conducted Susceptibility, Power Leads, (30 Hz to 150 kHz)**.
For Air Force aeromedical aircraft applications, conducted susceptibility was tested throughout the entire frequency band, from 30 Hz to 150 kHz. This test determined the component's ability to withstand ripple voltages associated with allowable distortion of power source voltage waveforms.

5. **CS114 - Conducted Susceptibility, Bulk Cable Injection, (10 kHz to 400 MHz)**. For Air Force aeromedical aircraft applications conducted susceptibility was tested throughout a narrower portion of the frequency band, from 10 kHz to 200 MHz. This test determined whether simulated currents that will be developed on platform cabling from electromagnetic fields generated by antenna transmission would affect the equipment under test.

6. **CS115 - Conducted Susceptibility, Bulk Cable Injection, Impulse Excitation.** This test evaluated the M Series resistance to the fast rise and fall time that may be present due to platform switching operations and external transient environments such as lightning and electromagnetic pulse.

7. **CS116 - Conducted Susceptibility, Damped Sinusoidal Transients, (10kHz to 100 MHz)**. This test procedure is used to verify the ability of the M series to withstand damped sinusoidal transients coupled onto the device's associated cables and power leads. This requirement is applicable to all interconnecting cables, including power cables, and individual high side power leads.

During emissions testing, all options were operating for the duration of the test to create the worst case emissions scenario. These tests were accomplished in both pacing and monitoring modes. Throughout the testing, the recorder (printer) ran continuously and the QRS beep sounded at maximum volume. For susceptibility testing, the ZOLL M Series was operated in the pacing mode and in the monitoring mode. In the pacer mode, settings were at 70mA and 70

BPM when pacer was activated. In the monitoring mode, the paddles were charged and discharged at intervals for two reasons. First, it allowed researchers to determine if EMI would cause the equipment to defibrillate at times other than when the operator depressed the discharge buttons. Second, energy defibrillation levels and monitor function could be confirmed. AFMEDL personnel were unable to test the SYNC function because it would have required them to be subjected to dangerous levels of electromagnetic radiation. For both emissions and susceptibility testing, the M Series were tested for operation on 115VAC/60Hz and internal battery power.

THERMAL/HUMIDITY

Extreme temperature and humidity testing is critical to determine if aeromedical equipment can be stored and operated during severe environmental conditions without experiencing physical damage or deterioration in performance. Extreme environmental conditions can have numerous incapacitating effects on medical equipment including, but not limited to the following: changes in material characteristics and material dimensions, possible overheating, changes in lubricant viscosity, changes in electronic components, and electronic or mechanical failures due to rapid water or frost formation.

Testing was conducted in the Air Force Research Laboratory (AFRL) research chambers operated and monitored by chamber operations personnel assigned to the Protective Systems Branch (HEPR) of the Biodynamics Protection Division at AFRL, Brooks AFB, TX. Each ZOLL M Series was placed in the center of the environmental chamber. All input and output cables and wires were routed through a port in the chamber wall, which was subsequently sealed with a precut sponge plug. The other components of the test setup remained outside the chamber. For operational tests, the M Series was monitored continuously and a performance check was conducted every fifteen minutes. For storage tests, the M Series was placed in the chamber and remained non-operational throughout the storage portion of the test. It was then placed outside the chamber and brought to laboratory ambient conditions for 30 minutes before conducting an operational test. The following describes the conditions of the environmental tests performed:

a. Humidity: 94 ± 4% RH, 85°F ± 3.6°F (29.5°C ± 2°C) for 4 hrs

b. Hot Temp Operation: 120°F ± 3.6°F (49°C ± 2°C) for 2 hrs

c. Cold Temp Operation: 32°F ± 7.2°F (0°C ± 4°C) for 2 hrs

d. Hot Temp Storage: 140°F ± 3.6°F (60°C ± 2°C) for 6 hrs

e. Cold Temp Storage: -40°F ± 3.6°F (-40°C ± 2°C) for 6 hrs

HYPOBARIC

Testing was conducted at the Air Force Research Laboratory (AFRL) chambers operated and monitored by chamber operation personnel assigned to the Protective Systems Branch (HEPR) of the Biodynamics Protection Division at AFRL, Brooks AFB, TX.

1. Cabin Pressure/Altitude: Altitude testing is critical for aeromedical evacuation equipment due to the potential effects of barometric pressure changes on the equipment. A majority of the aircraft, which are characterized as opportune aircraft available for use in aeromedical evacuation, pressurize their cabin atmosphere to barometric pressures equivalent to 8,000-10,000 feet above sea level. The differences in pressures can be critical to the effective operation of some medical equipment. Altitude testing consisted of operating the M Series while ascending from ground level to 10,000 ft, 12,500 ft and 15,000 feet. Performance checks were conducted at each altitude to assess both units. The same performance checks were conducted during decent back to ground level, at rates of 5000 ft/min, while stopping at 12,500 ft and 10,000 ft to allow for additional performance checks.

2. Rapid Decompression Testing: Rapid decompressions are caused by the loss of aircraft cabin pressurization and subsequent pressure equalization with ambient atmospheric pressures. It is important to determine how medical equipment will function during and after such a decompression to ensure that it will not endanger a patient, the aircrew personnel, or the aircraft itself. The M Series operated inside the rapid decompression test chamber as the chamber was pressurized to an equivalent of 8,000 ft (2,438 meters) altitude. Then, the chamber altitude was brought to 40,000 ft (12,192 meters) over a period of 60 seconds, held at 40,000 ft for a few minutes, and then returned to ground at a rate of 10,000-12,000 ft/min. The test was repeated twice with the decompressions occurring over seven and one seconds, respectively. The M Series was monitored throughout the series of decompressions, including performance checks each time the unit returned to ground. The simulator equipment remained outside the chamber. Simulator sensor cables and M Series power cord were passed through putty sealed access ports in the chamber wall.

EXPLOSIVE ATMOSPHERE

Testing was performed at the WRALC/TIECD (Engineering Test Facility) Robins AFB, Georgia. This test is conducted to assess the unit's ability to not ignite a fuel mixture in a reduced hypobaric environment under simulated flight conditions. Testing is conducted based on guidance found in Mil-Std 810F, Method 511.4. A test report was generated at the end of testing and forwarded to AFMEDL for inclusion in this technical report (11).

AIRBORNE PERFORMANCE

Airborne performance evaluations are a cost-effective and invaluable means of validating a piece of equipment's clinical and operational suitability under actual operating conditions. By carefully evaluating medical equipment items in their actual environment,

explosive atmosphere hazard. The M Series operated within expected parameters when subjected to environmental extremes and simulated cabin altitudes and did not demonstrate the potential for being a hazard to patients or crews during rapid decompression.

2. The following comments and recommendations apply to the M Series MonoPhasic and BiPhasic while in the aeromedcial evacuation environment:

   A. In certain aircraft such as the C-130/C-141, special training considerations may apply. Consider limitations due to aircraft ambient noise limiting audio alarms. Audible alarms were severely degraded while onboard C-130H aircraft due to high ambient noise levels inflight. The M Series MonoPhasic and BiPhasic should be positioned to allow visual alarm monitoring by aeromedical evacuation crewmembers throughout all phases of flight.

   B. On military C-9A aeromedical aircraft, the audible cues could be clearly heard and understood within 6-10 feet of the M Series MonoPhasic and BiPhasic units without the use of hearing protection.

   C. No transport case was evaluated. Care needs to be taken during transport to prevent damage to the M Series MonoPhasic and BiPhasic units. However, the manufacturer provided an Xtreme Pack to protect the units from harsh use. AFMEDL found the Xtreme pack useful in preventing damage during rough handling and did not interfere with normal use.

RECOMMENDATIONS

The following recommendations and operational restrictions accompany the airworthiness approval of the M Series:

1. Attach a warning label on the power cord that reads, **"Do not operate on 115VAC/400 Hz."**

2. Attach a warning label near the battery well that reads, **"Place battery in well before operating from 115VAC/60Hz."**

3. Inform aircraft commander during pre-mission briefing that the M Series monitor will be used inflight, and notify the aircraft commander if defibrillation is to occur due to the possibility of electromagnetic interference with aircraft navigation and communication equipment.

4. AFMEDL does not recommend that ZOLL Battery PD4410 or ZOLL Smart Battery PD4410 from the MonoPhasic and BiPhasic units be used with the ZOLL PD 4420 Battery Support System due to manufacturer's warnings about 4410 batteries overheating without special precautions being taken.

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REFERENCES

1. ZOLL Medical Inc., M Series, Operator's Manual.
2. Mil-Std 461E, Electromagnetic Emission and Susceptibility Requirements for the Control of Electromagnetic Interference.
3. Mil-Std 810F, Environmental Test Methods and Engineering Guidelines.
4. Mil-Std 1472, Human Engineering Design Criteria for Military Systems, Equipment, and Facilities.
5. Emergency Care Research Institute (ECRI).
6. Air Force Medical Equipment Development Laboratory Flight Performance Evaluation Procedures Guide and Testing Standards, Protective Systems Branch
7. National Fire Protection Agency (NFPA) 99, Health Care Facilities Code.
8. AFI 41-203, Electrical Shock Hazards.
9. AFI 41-201, Equipment Management in Hospitals.
10. Mil-Std 461E EMI Test Report #B00-4, AFRL/SNZW, WPAFB, OH
11. Explosive Atmosphere Test, Project 200052, WRALC/TIECD, Robins AFB, GA

APPENDIX

MANUFACTURER'S SPECIFICATIONS OF THE ZOLL MEDICAL, INC. M SERIES

SPECIFICATIONS

General

Size	6.8 in high x 10.3 in wide x 8.2 in deep (17.3 cm high x 26.2 cm wide x 20.8 cm deep)
Weight	11.5 lbs. (5.23 kg) with Multi-Function Cable and battery; 13.5 lbs. (6.14 kg) with paddles
Power	Sealed lead acid battery; 2V/cell, 5 cells, wired in series
AC Power	100-120 ~ 50/60 Hz, 220-240 ~ 50 Hz, 1.9A
Design Standards	Meets or exceeds UL 2601, AAMI DF-39, AAMI DF-2, and IEC 601-2-4.
Patient Safety	All patient connections are electrically isolated
Environmental	Operating Temperature: 0° to 55° C Storage and Shipping Temperature: -40° to 60°C Humidity: 5 to 95% relative humidity, non-condensing Vibration: Mil Std 810E, Minimum Integrity Test Shock: IEC 68-2-27, 50g 6mS half sine Operating Pressure: 594 to 1060 mBar Material Ingress: IEC 529, IP23 Electromagnetic Compatibility (EMC): CISPR 11 Class B-Radiated and Conducted Emissions Electromagnetic Immunity: AAMI DF-2 : IEC 1000-4-3 to 20 V/m Electrostatic Discharge: AAMI DF-2 : IEC 1000-4-2 Conducted Susceptibility: IEC 1000-4-4, 1000-4-5, 1000-4-6

Pacemaker (Pacer Version Only)

Type	VVI demand; asynchronous (fixed rate) when used without ECG leads
Pulse Type	Rectilinear, constant current
Pulse Duration	40 milliseconds ± 2%
Pulse Amplitude	Variable to 140 mA
Pacing Rate	Variable from 30 to 180 ppm
Output Protection	Fully defibrillator protected and isolated

Defibrillator

Waveform	Damped sinusoid.
Energy Selection	Selectable at 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 30, 50, 100, 150, 200, 300, 360 joules
Charge Time	Less than 7 seconds with a new fully charged battery (first 15 charges to 360 Joules). Depleted batteries will result in a longer defibrillator charge time
Energy Display	Monitor display indicates both selected and delivered energy
Charge Controls	Control on apex paddle and on device front panel
Paddles	Standard anterior/anterior adult and pediatric. Adult paddles slide off to expose pediatric paddles
Multi-Function Electrode Pads	Specifically designed adult anterior/posterior pre-gelled ZOLL MFE Pads, and MultiFunction Stat Padz
Defibrillation Advisory	Evaluates electrode connection and patient ECG to determine if defibrillation is required

ECG Monitoring

Patient Connection	3 lead ECG cable, 5-lead cable, paddles or MFE Pads. Selectable by front panel switch
Input Protection	Fully defibrillator protected. Special circuit prevents distortion of ECG by pacer pulse
Implanted Pacemaker Spike Display	Dedicated circuitry detects most implanted pacemaker spikes and provides standard display marker of spike on ECG trace
Bandwidth	0.5-40 Hz (-3dB) standard/0.05-130 Hz Diagnostic
Lead Selection	Displayed on monitor
ECG Size	0.5, 1, 1.5, 2, 3 cm/mV – display on monitor
Heart Rate Alarm	On/Off displayed on monitor. User selectable, Tachycardia 60-280 bpm, Bradycardia 20-100 bpm
1 Volt ECG Out	1.0 Volt/cm of deflection on strip chart recorder. < 25ms delay from patient ECG input
Display Format	Non-fade moving bar display

Display

Screen Type	High resolution field emission display
Screen Size	5 inches diagonally (12.7 cm)
Sweep Speed	25 mm/second
Viewing Time	4 seconds

Recorder

Paper	80 mm thermal (grid width) 90 mm (paper width)
Speed	12.5, 25 mm/second (user selectable)
Delay	6 seconds

Annotations	Time, date, defib energy, heart rate, pacer output, QRS sync marker, ECG size, lead, alarm, defib test OK/Fail, analyze ECG, Pads off, analysis halted, noisy ECG, shock advised, no shock advised, ECG too large, and diagnostic bandwidth.
Printing Method	High resolution, thermal array print head.
Print-out Modes	Manual or automatic – user configurable.
Control	Front panel and paddle.
Automatic Function	15 second recording initiated by alarm activation or defibrillator discharge.

Battery Packs

Type	Rechargeable, sealed lead acid.
Weight	1 kg (2.2 lbs)
Voltage	2V/cell; 5 cells wired in series.
Recharge Time	4 hours or less with integral charger.
Low Batter Indicator	Message displayed on monitor and 2-beep low battery tone sounds every minute until just before shutdown, when it will beep twice every 2 seconds. The time from display of the "LOW BATTERY" or "REPLACE BATTERY" message until the instrument shuts down will vary depending upon the battery age and condition
Operating	For a new, fully charged battery pack at 20° C: 35 defibrillator discharges at maximum energy (360J), or 2.5 hours of continuous ECG monitoring/pacing at 60 mA, 80 beats/minutes